.decimal®
The benchmark for custom radiation therapy

K083672

APR 13 2009

Section 5	510(k) Summary or 510(k) Statement

Section 807.87 (h) A 510(k) Summary as described in Section 807.92 or a 510(k) statement as described in 807.93

Premarket Notification [510(k)] Summary as required by 21 CFR 807.92

Date summary was prepared:

February 2009

Submitter's Name:

.decimal, Inc.
121 Central Park Pl
Sanford, Florida 32771

Contact Person:

Daniel L. Bennett
Director of Quality and Regulatory Affairs
Phone: 407-330-3300
Fax: 407-322-7546
Email:dbennett@dotdecimal.com

Device Name:

p.d

Classification Name:

90 MUJ
21 CFR892.5050
Class II

Predicate Device(s):

.decimal Inc. p.d (K061440)

Intended Use:

The p.d software is used by radiation therapy professionals to assist in the treatment of cancer patients. The p.d software takes a Treatment Planning System design of a compensating filter which contains steep, narrow, and unmachinable areas and then smoothes them out into a machinable surface. And the software converts Treatment Planning System compensator filter file into a .decimal file format.

Optionally the user may elect to design a beam shaping compensator filter based on Treatment Planning System's data which will be transferred back into the Treatment Planning System for final dose verification. The customer uses the software in-house before sending the file to .decimal to be manufactured. Each filter must be QA'd and approved by a radiation therapy professional prior to use on a patient.

Summary of Technological Characteristics:

The device features of p.d are similar to the predicate device (p.d K061440 originally submitted in 2006). They both take the design of a compensating filter used for radiation therapy which contains steep, narrow, and unmachinable areas and then smoothes them out into a machinable surface. It also allows the user to design a beam shaping compensator filter based on Treatment Planning System's data. The target population is identical and the use parameters are also very similar.

A detailed comparison can be found in section 12 of this submittal.

Summary of Clinical Testing:

Clinical testing is not required to demonstrate substantial equivalence or safety and effectiveness of this device. Clinically oriented validation test cases were written and executed by in house .decimal customer support personnel including Board Certified Medical Physicists. This can be found in section 16-9 of this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2009

Mr. Daniel L. Bennett
Director of Quality and Regulatory Affairs
.decimal, Inc.
121 Central Park Place
SANFORD FL 32771

Re: K083672
Trade/Device Name: p.d
Regulation Number: 21 CFR §892.5050
Regulation Name: Medical charged-particle radiation therapy system
Regulatory Class: II
Product Code: MUJ and IXI
Dated: February 18, 2009
Received: February 26, 2009

Dear Mr. Bennett:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

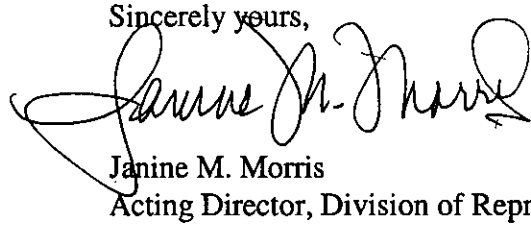
If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxx	(Gastroenterology/Renal/Urology)	(240) 276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	(240) 276-0115
21 CFR 892.xxx	(Radiology)	(240) 276-0120
Other		(240) 276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at 240-276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,



Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

.decimal®

The benchmark for custom radiation therapy

Section 4	Indications for Use Statement

510(k) Number (if known) K083672

Device Name: p.d

Indication for Use: The p.d software is used by radiation therapy professionals to assist in the treatment of cancer patients. The p.d software takes a Treatment Planning System design of a compensating filter which contains steep, narrow, and unmachinable areas and then smoothes them out into a machinable surface. And the software converts Treatment Planning System compensator filter file into a .decimal file format.

Optionally the user may elect to design a beam shaping compensator filter based on Treatment Planning System's data which will be transferred back into the Treatment Planning System for final dose verification. The customer uses the software in-house before sending the file to .decimal to be manufactured. Each filter must be QA'd and approved by a radiation therapy professional prior to use on a patient.

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K083672